The Importance of Post-Cured Tubing in Sanitary Applications

New research is highlighting concern about the migration of silicon from tubing into final pharmaceutical products. Here's a look at platinum-cured tubing that destroys the dangerous contaminants that can migrate into consumable products.

By Chuck Treutel, P.E.

Silicone tubing plays a key role in pharmaceutical and biopharmaceutical manufacturing processes and, as with the raw chemical ingredients and excipients used to produce drugs and medicines, is similarly subject to stringent quality controls. Meeting the requirements of regulatory authorities such as the FDA and the European Medicines Agency (EMEA) is always uppermost in a pharmaceutical manufacturer's mind.

New research has highlighted concern about failures in the post-curing process of silicone tubing production. One of the key concerns is the migrating of silicon from the tubing into the final product, a phenomenon that would bring about harmful consequences for patients. In recent years, a number of studies on leachables for pharmaceutical products and medical device have been undertaken.

Toxicon Tests

Now, new research from the independent specialist laboratory Toxicon indicates that pharmaceutical manufacturers may unknowingly be using tubing capable of generating leachables during the production process. Toxicon carried out tests on three different types of platinum-cured tubing from three different suppliers and found that two of the three tested produced levels of leachables in the product that many pharmaceutical manufacturers did not anticipate being present.

The possible migration of contaminants from tubing into consumable products has serious implications for pharmaceutical manufacturers. The tests conducted by Toxicon have established that the cyclic siloxanes generated are cytotoxic with a reduction in cell count of 70 percent. Research available from the Danish Environmental Protection Agency cites toxicity studies demonstrating the potential carcinogenic effects of cyclic siloxanes D4 (octamethylcyclotetrasiloxane), D5 (decamethylcyclopentasiloxane), and short-linear HMDS (hexamethyldisiloxane). The liver is the main target organ for D4 while the primary target organ for D5 exposure by inhalation is the lung.

The laboratory concluded that the inclusion of a comprehensive post-curing stage in the final process of the unaffected tubing played a key role in ensuring the following:

1. The curing reaction was fully completed.
2. Any unwanted volatiles (extractable linear and cyclic siloxanes) were driven off from the tubing, however, during the process stages.

Selection Notes

Many pharmaceutical manufacturers use platinum-cured tubing in both validated

and non-validated manufacturing processes because of the assumption that platinum curing guarantees the required level of purity and low/safe levels of extractables. Some tubing manufacturers go so far as to specifically state that platinum-cured tubing eliminates the worry of leaching volatile by-products.
Of course, tubing is not simply a commodity product. Wide variations in manufacturing and post-curing processes mean that various tubing from different manufacturers have different and distinct characteristics and, therefore, cannot be selected on a straightforward “comparing with the like” basis. As the Toxicon tests indicated, both the type of manufacturing and the post-curing process play significant roles in determining the levels of leachables present in the tubing itself.
One manufacturing solution that destroys the dangerous contaminants that could potentially migrate into consumable products is Pumpsil platinum-cured tubing. A high purity, “addition cured” silicone tubing produced from a USP class VI raw material, Pumpsil exhibits a number of key features including high purity levels, no polychlorinated biphenyls (PCBs), no 2,4-dichlorobenzoic acid (2,4-DCBA) residues, very tight surface cure, and very low levels of leachables. It also got a clean bill of health in the recent Toxicon tests. The post-curing process used to drive off the extractable linear and cyclic siloxanes that are generated in silicone tubing production guarantees a very high level of purity. During this stage, high temperatures are used in the post-cure ovens and completely change the air every 2.5 minutes. This is the key to achieving the high purity that is integral to the manufacturing process and ensures that volatiles are stripped off and removed.

Proactive Approach

With independent research now highlighting potential risks, the likelihood is that major regulatory bodies, including the FDA and EMEA, will turn their attention in this direction and maintain an active interest in these tubing issues.
Given the stakes involved, pharmaceutical manufacturers are likely to take a proactive approach by asking their tubing suppliers pressing questions about the extent of their post-curing process.
Eventually, this may even extend to the revalidation of existing processes and suppliers. In a highly competitive, tightly regulated marketplace, no manufacturer can afford to lose batches or risk product recalls at the hands of their manufacturing process.
In conclusion, peace of mind and confidence in the supply chain are critically important. Tubing suppliers may tell end-users one thing; however, the onus is ultimately on pharmaceutical manufacturers to ensure that the tubing they are using is not negatively impacting their products.
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